IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#11 A.Q.J 9/18/99 (NE)

APPLICATION OF:	Bazin, et al.		
SERIAL NO:	09/056,072	GROUP ART UNIT:	1644
FILED:	April 7, 1998	EXAMINER:	Gambel
FOR:	LO-CD2a Antibody and Uses Thereof for Inhibiting T-Cell Activation and Proliferation		

Assistant Commissioner of Patents and Trademarks
Washington, DC 20231

SIR:

In response to the Final Rejection dated April 13, 1999, reconsideration of the above-identified application is hereby respectfully requested.

Claims 30-32, 35-40, and 43 stand rejected under 35 U.S.C. 102(b) as being anticipated by Xia, et al.

The claims stand rejected under 35 U.S.C. 103 as being unpatentable over Xia, et al. in view of Queen, et al. or Newman, et al. and in further view of Guckel, et al. or Bromberg, et al. or Hafler, et al. or Chavin, et al. or Faustman.

These rejections are respectfully traversed.

The Examiner has taken the position that Xia teaches the LO-CD2a specificity and relies upon a number of characteristics to distinguish this specificity, including distinguishing the LO-CD2 specificity from other CD2-specific antibodies. The Examiner also states that while the characteristics disclosed by the prior art may be common to certain classes of CD2-specific antibodies, Xia clearly distinguishes the LO-CD2a antibody specificity from other CD2-specific

antibodies, including providing a number of characteristics and comparisons that would lead to an expectation of success of antibodies that bind the same epitope as the LO-CD2a antibody.

Applicants respectfully disagree. As noted previously, Applicants submitted a copy of a Declaration by Dr. Barbara A. Bierer which was filed in parent application Serial No. 08/472,281. In such Declaration. Dr. Bierer stated that the characteristics which are defined in Xia, et al. are not characteristics which define a specific epitope, but rather, such characteristics are characteristics which are common to CD2 antibodies as a class. As stated by Dr. Bierer, from the teachings of Xia, one skilled in the art would have no way of knowing which, if any, of the antibodies which would be produced by the general procedure disclosed by Xia, et al. is LO-CD2a or which binds to the same epitope as the antibody of the present invention in that the characteristics disclosed by Xia do not define LO-CD2a uniquely (distinguishing LO-CD2a from CD2 antibodies as a class) or define which antibodies bind to the same epitope as LO-CD2a or the deposited antibody. Because Xia does not disclose characteristics which define a specific epitope, Xia, contrary to the Examiner's assertions, does not provide sufficient guidance and direction to distinguish the LO-CD2a antibody specificity.

In order to negate the patentability of the claimed invention, it is incumbent upon the Examiner to provide detailed reasons as to why he believes that the characteristics of Xia uniquely define antibodies which bind to the same epitope as the antibody produced by the deposited cell line, particularly in view of the Declaration of Dr. Bierer, which indicates clearly that the characteristics included in Xia, et al. are characteristics which are known to be present in CD2 antibodies as a class, and do not define whether or not an antibody binds to a particular epitope. In particular, as noted by Dr. Bierer, different antibodies which bind to different epitopes have the

characteristics disclosed by Xia and, therefore, such characteristics may not be used for identifying an antibody as claimed.

Simply put, the Examiner has provided a reference which discloses characteristics of CD2 antibodies as a class. Such characteristics are not related to a specific epitope. Therefore, the Examiner cannot assert that Xia anticipates the claimed invention or renders the claimed invention obvious to one of ordinary skill in the art.

Although Xia at Page 320 indicates that the LO-CD2a antibody binds to an epitope which is different from other antibodies referenced to on Page 320, Xia does not identify the epitope to which LO-CD2a binds. Because Xia does not define the epitope, Xia does not make LO-CD2a available to those skilled in the art, and one skilled in the art would not have sufficient information to determine whether a produced antibody bound to the same epitope as LO-CD2a. The information provided on Page 320 at best permits one skilled in the art to determine that a produced antibody is not D66. Such information does not enable one to determine whether a produced antibody is LO-CD2a, or an antibody other than LO-CD2a.

Also, contrary to the Examiner's assertions, the prior art does not provide any reasonable expectation that the claimed antibody or a composition including such antibody in combination with a pharmaceutically acceptable carrier could be used successfully in a human. In fact, the prior art, taken as a whole, suggests that CD2 antibodies would not be successful.

Applicants have noted previously that the Thurlow and Giorgi references reported that attempts to use CD2 antibodies in a human or a primate were not successful.

In contrast, Applicants provide human data at Pages 40-43 of the specification. Such data shows that the claimed antibody can reverse rejection successfully.

In the Guckel reference, cited by the Examiner, it was stated that CD2 antibodies, if effective at all, would be effective only if administered after T-cell priming. In treating rejection or other T-cell mediated responses, however, it is virtually impossible to treat within 24 hours of antigen "priming."

Therefore, not only would the ability to treat patients successfully in accordance with the present invention not be expected from the prior art, but also, the prior art suggests that CD2 antibodies would not be suitable for the treatment of patients.

Applicants, therefore, have found unexpectedly that the claimed antibody may be employed to treat humans, contrary to the accepted wisdom of the prior art. Such findings are a clear indication of the nonobviousness of the claimed antibody as employed in combination with an acceptable pharmaceutical carrier for treating humans.

In addition, even if, assuming solely for the sake of argument, that the claimed antibody were known, the cited prior art does not render obvious to one of ordinary skill in the art the combination of the claimed antibody and an acceptable pharmaceutical carrier because the prior art does not disclose or even remotely suggest to one of ordinary skill in the art that the claimed antibody may be used to treat humans.

Thus, for the above reasons and others, the cited prior art does not render the present claimed invention obvious to one of ordinary skill in the art within the meaning of 35 U.S.C. 103, and it is therefore respectfully requested that the rejection under 35 U.S.C. 103 be reconsidered and withdrawn.

Regarding the rejection under 35 U.S.C. 112, second paragraph, of Claims 34 and 42, the term "chimeric" is well known to those skilled in the art. Therefore, such term does not render the claims indefinite. Because the term is well known to those skilled in the art, one skilled in the art

could determine readily whether a particular antibody is a chimeric antibody and whether such an antibody binds to the same epitope on human lymphocytes as the antibody produced by the deposited cell line, and thus infringe Claims 34 and/or 42. For the above reasons and others, Claims 34 and 42 are not indefinite, and it is therefore respectfully requested that the rejection under 35 U.S.C. 112, second paragraph, be reconsidered and withdrawn.

For the above reasons and others, this application is in condition for allowance, and it is therefore respectfully requested that the rejections be reconsidered and withdrawn and a favorable action is hereby solicited.

Respectfully submitted,

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Signature

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